

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-357V

Filed: September 18, 2015

VERA IVANCHUK, as mother and
Natural guardian, and ANDREY
IVANCHUK, as father and natural
Guardian of Y.I.,

Petitioners,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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Finding of Fact; Surgical Intervention;
Special Processing Unit ("SPU")

Jeffrey Pop, Pop & Associates, Beverly Hills, CA, for petitioners.

Christine Becer, U.S. Department of Justice, Washington, D.C., for respondent.

RULING ON FACTS¹

On April 9, 2015, Vera and Andrey Ivanchuk ["petitioners"] filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq, [the "Vaccine Act" or "Program"] on behalf of their minor daughter, Y.I. The petition alleges that following the April 17, 2012 administration of a number of vaccinations, including Measles Mumps and Rubella ("MMR"), Y.I. experienced Thrombocytopenic Purpura ("ITP"). Petition at 1. The case was assigned to the Special Processing Unit ["SPU"].

I. Procedural History

An initial status conference was held with the staff attorney managing this case on June 22, 2015. During the status conference, petitioners' counsel confirmed that petitioners were alleging that Y.I.'s spinal tap and bone marrow biopsy, conducted

¹ Because this unpublished ruling contains a reasoned explanation for the action in this case, it will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

under anesthesia, constituted a “surgical intervention” in satisfaction of the Vaccine Act’s severity requirement at §300aa-11(c)(1)(D). See Scheduling Order, June 22, 2015 (ECF No. 9). In a status report of July 27, 2015, respondent’s counsel indicated that upon review of the case, her client wished to file a Rule 4(c) report. See Status Report, July 27, 2015 (ECF No. 10). In subsequent e-mail communication with the court’s staff attorney, respondent’s counsel confirmed that her client was opposed to settlement and wished to have a status conference with the Chief Special Master to discuss petitioner’s contention that Y.I.’s bone marrow biopsy constituted a surgical intervention.²

On September 17, 2015, I held a status conference with the parties. During the call I indicated that I intended to rule on the question of whether Y.I.’s bone marrow biopsy constitutes a surgical intervention for Program purposes. Respondent’s counsel raised and preserved respondent’s objection to my ruling.

II. Facts

Y.I. was born on December 29, 2008. Ex. 1, p. 1. On April 17, 2012, she was seen for her 3 year well child check-up at which she received the following vaccinations: DTap-HIB-IPV, Hepatitis A, Pneumococcal Conjugate, MMR, and Varicella. Ex. 2; Ex. 5, pp. 1-3.

Approximately one week later, on April 28, 2012, Y.I.’s mother reported unusual bruising following a “minor bump.” Ex. 1, p. 2; Ex. 7, p. 18. The bruise worsened the following day, and Y.I. also developed petechia, gingival bleeding, and bloody urine. *Id.*

On April 29, 2012, Y.I. was admitted to the emergency department on stretcher via EMS and her case was classified as “urgent.” Ex. 7, pp. 127-28. She was diagnosed with “severe” thrombocytopenia, having a platelet count of 2,000. Ex. 7, p. 19. She remained hospitalized for 10 days. Ex. 7, p. 18-20.

Initially, Y.I. was given two rounds of IVIG.³ Ex. 7, p. 19. She experienced clinical improvement, but no change in her platelet count. *Id.* She was later given prednisolone, an oral steroid, beginning May 3, 2012, which improved her thrombocytopenia by May 8, 2012, her discharge date. *Id.* During her hospitalization, Y.I. underwent a bone marrow aspiration and biopsy “to rule out myeloproliferative disease prior to starting oral steroids.” *Id.*

Although Y.I. continued to have follow-up appointments to monitor her platelet counts in the several months following discharge, petitioners do not contend that Y.I.’s ITP persisted for at least six months. Petition at 3.

² At the time of respondent’s counsel’s request, this case was on the docket of then Chief Special Master Vowell. The case was transferred to my docket on August 7, 2015. See Notice of Reassignment, August 7, 2015 (ECF No. 12).

³ Petitioners have *not* alleged that Y.I.’s IVIG treatments constituted a surgical intervention.

III. Discussion

In order to state a claim under the Vaccine Act, a vaccinee must have either:

(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention.

§300aa-11(c)(1)(D).

There is no definition of “surgical intervention” within the Vaccine Act. See §300aa-33 (Definitions). Nor is there any Federal Circuit decision interpreting that term. As described in prior decisions by special masters, the “surgical intervention” language was added to the Vaccine Act to allow for recovery for intussusception, which often requires surgery but does not typically persist for six months. See, e.g. *Spooner v. HHS*, No. 13-159V, 2014 WL 504728 (Fed. Cl. Spec. Mstr. Jan. 16, 2014); *Stavridis v. HHS*, No. 07-261V, 2009 WL 3837479 (Fed. Cl. Spec. Mstr. Oct. 29, 2009).

In *Spooner*, the special master interpreted surgical intervention as “the treatment of a disease, injury and deformity with instruments or by the hands of a surgeon to improve health or alter the course of a disease.” 2014 WL 504278, *10. In that case, the special master based his definition of surgical intervention on entries from *Dorland’s Illustrated Medical Dictionary* (29th Edition). 2014 WL 504278, *10. He noted that the Federal Circuit has approved of the use of medical dictionaries to define medical terms. *Id.* (citing *Abbot v. HHS*, 19 F.3d 39 (Fed. Cir. 1994)). I agree with the definition of surgical intervention identified in *Spooner*.⁴

In *Spooner*, utilizing the above definition, the special master determined that a lumbar puncture conducted under general anesthesia was surgical in nature, but did not constitute an “intervention,” because it was diagnostic and not necessary for treatment. *Id.* at 12. Conversely, he determined that IVIG, though for treatment, was not surgical in nature. *Id.*

⁴ I do note that in the earlier *Stavridis* decision, the chief special master rejected essentially the same definition adopted in *Spooner*, contending that it was overly broad. 2009 WL 3837479, *4. In that case, the chief special master accepted the un rebutted opinion of respondent’s medical expert that steroid treatments and blood transfusions should not be understood as surgical interventions. *Id.* at *6. That decision did acknowledge, however, that there is a “large gray area between treatments that are definitely considered ‘surgical intervention’ and those that are not.” *Id.* at *6. In this case, I find that the medical records offer sufficient detail to address this issue without the need for further medical opinion. I also note that in this case respondent’s counsel cited approvingly to the *Spooner* decision during the status conference.

In this case, there is no question that Y.I. underwent a surgical procedure. In order to perform the bone marrow aspiration and biopsy, Y.I. was placed under anesthesia and the procedure was performed by a physician. See, e.g. Ex. 7, p. 1, 190. A preoperative checklist was completed. Ex. 7, pp. 130-31. Her mother signed a consent for an operative procedure.⁵ The authorization form identified possible risks of pain, bleeding and infection. Ex. 7, pp. 5-6. Following the procedure, Y.I. was monitored with Aldrete scoring to assess her recovery from anesthesia. Ex. 7, p. 4.

I also find that Y.I.'s bone marrow aspiration and biopsy constituted an intervention. Although a bone marrow biopsy is in itself not a treatment that alters the course of a disease or condition, under the facts of this case that is an incomplete characterization.⁶ Y.I.'s medical records indicate that "a bone marrow biopsy was performed to rule out myeloproliferative disease prior to starting oral steroids . . ." Ex 7, p. 19. The same record indicates that the oral steroid effectively improved Y.I.'s ITP. *Id.* Because the medical record explicitly indicates that the bone marrow biopsy was required in order to institute treatment, the bone marrow biopsy was a necessary and integral part of the overall treatment protocol that ultimately cured Y.I.'s ITP. I also find it significant that at three years of age at the time of the procedure, Y.I. was incredibly young. It is highly unlikely that her treating physician would have subjected her to an invasive procedure of this nature without sufficient need.⁷

Finally, I note that this finding is narrowly tailored to the facts and circumstances presented by this case. It is *not* a finding that bone marrow biopsy constitutes a surgical intervention in all circumstances.

IV. Conclusion

For all these reasons, I find that Y.I. experienced hospitalization and surgical intervention within the meaning of §300aa-11(c)(1)(D)(iii) of the Vaccine Act.

s/ Nora Beth Dorsey

Nora Beth Dorsey
Chief Special Master

⁵ The authorization form used in Y.I.'s case is titled "Authorization for Administration of Anesthesia and for Performance of Operations and Other Procedures." Ex. 7, pp. 5-6.

⁶ During the status conference, respondent's counsel argued that a bone marrow biopsy is a diagnostic procedure and that under the reasoning in *Spooner*, petitioners' claim should be dismissed. I find, however, that this case is factually distinct from *Spooner*. Of course, even if the facts of the two cases were identical, I am not bound by the decision of another special master.

⁷ It is also worth noting that, as described above, Y.I.'s bone marrow biopsy was performed in the course of a hospitalization following admission to the emergency department as an "urgent" case of "severe" ITP. In addition to the definition described in *Spooner*, *Dorland's Illustrated Medical Dictionary* also defines an intervention as "the procedures involved in responding to an emergency." *Dorland's* (32nd Ed.), p. 952. This suggests the need to identify appropriate treatment protocol on an urgent basis and provides additional rationale for considering the treatment protocol as a whole an "intervention."